REMARKS

I. OVERVIEW

Applicants have reviewed and considered the Office Action mailed September 17, 2007 and the reference cited therewith. Applicants gratefully acknowledge the withdrawal of the section 103 rejections by the Examiner. Claims 1, 6 and 8-9 have been amended. New claims 15 and 16 have been added to better describe the invention. Support for these amendments and new claims may be found throughout the specification, for example, at paragraphs 32, 90, 118 and 195-208 in the published application. No new matter has been added. Upon entry of this amendment, claims 1-16 are pending in the present application, with claims 11-14 remaining withdrawn from consideration. In light of the remarks that follow, Applicants respectfully request reconsideration and withdrawal of the rejections.

II. DOUBLE PATENTING REJECTION

Claims 1-10 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 14 of U.S. Patent No. 5,792,935 ('935) issued August 11, 1998. The Examiner states that because a species anticipates a genus, claim 14 of U.S. patent no. 5,792,935 anticipates claims 1 and 3 of the present application.

A. The '935 Patent Does Not Teach or Suggest Each Element of the Claims

Applicants respectfully traverse this rejection and respectfully submit that the present claims are not made obvious by the '935 patent as the '935 patent fails to teach or suggest all of the elements of Applicant's claimed invention. MPEP § 2142.

The Office Action, at page 4, seems to dismiss the Applicants' element of "expressing a recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge" as required by amended claim 1. Support for this amendment may be found throughout the specification, for example, at paragraphs 32 and 195-208 in the published specification. Claims 8 and 9 have been similarly amended. Because the '935 patent does not teach expressing the recombinant viral immunogen in a plant at a level such that upon oral administration of a composition comprising the viral immunogen an immunogenic response to the viral immunogen is elicited so that the animal is protected against viral challenge, the '935 patent does not teach all the limitations of claim 1 and therefore, claim 14 of the '935 patent cannot make obvious claim 1 or claim 3, nor claims 2, 4-10 and 15-16.

B. The '935 Patent Does Not Provide a Reasonable Expectation of Success.

Applicants respectfully submit that the present claims are not made obvious by the '935 patent as the '935 patent fails to provide a reasonable expectation of success. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP §§ 2142 and 2143.

The claimed method of the '935 patent directed to the transformation of bananas, while novel, does not suggest their broad use in making immunogenic substances that upon oral administration to an animal would elicit an immunogenic response to the viral immunogen so that the animal is protected against viral challenge, nor would there be any expectation of success in achieving such levels or such an immune response. Contrary to the Office Action at page 4, which states that "high levels of expression was well known in the art and the ability to elicit an

immune response is an inherent property of the hepatitis B surface antigen," Applicants point out that while high levels of plant proteins may have been achievable, there is no expectation of success that a viral mammalian protein would be capable of expression in a plant since the viral immunogen would normally only be expected to express in a mammal due to viral tropism. Moreover, since the viral mammalian protein relies solely on plant machinery for expression there would be no expectation that the protein would be properly folded such that it could elicit an immune response when orally administered to an animal and provide protection from viral challenge. Applicants strongly assert that neither the suggestion of all the elements of the claimed unique invention of the present application nor the expectation of success is taught in the '935 patent for one ordinarily skilled in the art. The '935 patent does not provide any data indicating that the hepatitis B surface antigen can actually be expressed in banana plants, much less provide any level of hepatitis B surface antigen expression or suggest that the expression levels achieved would be successful in eliciting an immune response that provided protection from viral challenge. Therefore, as asserted above, there is no expectation of success even in the mere expression of hepatitis B surface antigen in bananas, much less the genus of plants. Assuming *arguendo* that expression is achieved, there is no expectation that the immunogen would elicit upon oral administration an immunogenic response that provided protection from viral challenge. Thus, the '935 patent does not provide one of ordinary skill in the art a reasonable expectation of success for the claimed methods. Applicants respectfully submit that claim 14 of the '935 patent does not make obvious claims 1-10 and 15-16 of the present invention.

For at least these reasons, the '935 patent does not anticipate or make obvious claims 1-10 and 15-16. In light of the above, Applicants respectfully request that this rejection be withdrawn and reconsidered.

III. CONCLUSION

This amendment accompanies the filing of a Request for Continued Examination (RCE). Please charge Deposit Account No. 26-0084 the amount of $405.00 for the RCE per the attached transmittal.

No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,

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